Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEVIN J. PHILLIPS and GILBERT W. COLE

Appeal No. 2001-0931
Application No. 09/104,476

ON BRIEF

Before, WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we remand the application to the examiner to consider the following issues and to take appropriate action.

This appeal under 35 U.S.C. § 134 is from the examiner's final rejection of claims 1-9, which are all the claims pending in the application.[1] Claims 1, 3 and 5 are illustrative of the subject matter on appeal and are reproduced below:

1. A test strip for use with a photometer for determining blood glucose concentration from a blood sample, said strip comprising:

a substrate having a top surface and an opposing bottom surface, said substrate having an aperture formed therethrough,

[1] We note appellants' statement (Brief, page 1) that no claims are canceled and that claims 10-20 are withdrawn from consideration. This statement is in error. Claims 10-20 were canceled by appellants' amendment received December 30, 1999 (Paper No. 5).

said aperture being adapted to receive and receiving a droplet of blood;

a porous membrane having a top surface and an opposing bottom surface, said top surface of said membrane adhered to said bottom surface of said substrate so that said membrane is in registration with said aperture in said substrate, said porous membrane being adapted to filter and filtering red blood cells from plasma in said blood; and

a reagent carried on said bottom surface of said membrane, the interior of said membrane being substantially free of said reagent, said reagent being adapted to react and reacting with glucose in blood plasma

3. The test strip as recited in claim 1, wherein said membrane has a pore size larger than 0 microns and less than 1200 microns.

5. The test strip as recited in claim 1, wherein said substrate is pantone 420 C.

The references relied upon by the examiner are:

Phillips (Phillips I)	5,556,761	Sep. 17, 1996
Phillips et al. (Phillips II)	5,843,692	Dec. 1, 1998

GROUNDS OF REJECTION

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph as the specification fails to adequately describe the claimed invention.

Claim 1-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Phillips I, and appellants' specification in view of Phillips II.

DISCUSSION

Initially we note the examiner's statement (Answer, page 3), "[t]he copy of the appealed claims contained in the Appendix to the [B]rief is incorrect and does not reflect the amendments made to the claims in [P]aper #8 received 12/30/99." The examiner, however, failed to identify which claims were incorrectly copied. Upon review of Paper No. 8, pages 1-2 we find that claims 1, 3 and 5 were amended. Comparing these three claims to appellants' "Appendix of Claims Involved in the Appeal" (the Appendix) the only inconsistency we find is that the Appendix includes two claims numbered "3". Upon further inspection of the record, we find that the first occurrence of claim 3 (at page 11 of the Appendix) recites claim 3 as it was originally presented. At page 12 of the Appendix, claim 3 is noted as "amended" and reflects the changes made in the December 30, 1999 amendment.

Therefore, it appears that the examiner's concern is that the copy of the appealed claims contained in the Appendix includes two copies of claim 3, one of which is correct and is labeled "amended". If this is the examiner's only concern then the examiner should have clearly stated that the Appendix includes two copies of claim 3, and that the first occurrence on page 11 is not correct. We note however, that the examiner's failure to clearly and concisely explain his position follows through to the remaining issues on appeal.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 3), claim 3 is "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors [sic] … had possession of the claimed invention." We understand the examiner's statement of the rejection to be one of written description. The examiner finds (Answer, page 4), "[c]laim 3 has been amended to include the limitation of the pore size is larger than 0 microns. The specification teaches at several locations the pore size may be 250-1200 microns." We note the examiner's failure to identify where the specification discloses, "the pore size may be 250-1200 microns."

However, in responding to appellants' arguments (Answer, page 8) the examiner states "[i]t is the examiner's position that the specification is not enabling for any pore size and that the pore size may be a point of criticality of the invention which requires specific enablement and/or written description. Further, the function of the test strip is highly dependent upon the pore size." Notwithstanding the examiner's inclusion of the term "written description" in his argument, the issues raised by the examiner are clearly those of "enablement" and not "written description." As set forth in Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (CAFC 1991), "[w]ith respect to the first paragraph of §112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)."

Furthermore, to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

To assist the fact finder in meeting his initial burden of setting forth a reasonable explanation as to why he believes the scope of the claimed invention is not adequately enabled by the description, our appellate reviewing court has outlined a number of factors that should be considered. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

On this record, the examiner provides no analysis of the Wands factors. In addition, we find that the examiner failed to rely on any factual evidence to support his position. Instead, we find only the examiner's unsupported conclusions, tied together with the issue of written description, as to why the specification does not enable the claimed invention. For example, we note the examiner's failure to develop the record with regard to his comments that "the pore size may be a point of criticality" and "the function of the test strip is highly dependent upon the pore size." See id.

As set forth in Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1033 (Fed. Cir. 1997), "[f]or an appellate court to fulfill its role of judicial review it must have a clear understanding of the grounds for the decision being reviewed," which requires that "[n]ecessary findings must be expressed with sufficient particularity to enable [the] court without resort to speculation, to understand the reasoning of the board, and to determine whether it applied the law correctly and whether the evidence supported the underlying and ultimate fact-findings." Like the Court of Appeals in Gechter, this board requires a clear understanding of the grounds for the decision being reviewed. In this case, we find it difficult to understand the examiner's reasoning and whether the evidence upon which he relies supports the underlying fact-findings for the rejection under 35 U.S.C. § 112, first paragraph.

In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case under 35 U.S.C. § 112, first paragraph.

Accordingly we vacate the examiner's rejection, and remand the application to the examiner to provide him with an opportunity to reevaluate his position in light of the correct legal standards.

If upon review of the file wrapper and other relevant document, the examiner remains of the opinion that the claims on appeal are unpatentable, he should issue an appropriate Office action that sets forth the facts and reasons used in support of such a rejection.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

The examiner presents three issues under 35 U.S.C. § 112, second paragraph. First, the examiner finds (Answer, page 6) the phrases "being adapted to filter and filtering" and "being adapted to react and reacting" as they appear in claim 1 are "awkward and improper". Second, the examiner questions (Answer, bridging paragraph, pages 6-7), "how one would filter RBC's from plasma which does not contain RBC's." Third, the examiner states (Answer, page 7), "[c]laim 5 is queried, see page 8[,] line 23 of the specification."

At page 9 of the Answer, the examiner states "[t]his rejection is not addressed" by appellants. Therefore, appellants' Brief is defective. Appellants' Brief must be responsive to every ground of rejection stated by the examiner. See The Manual of Patent Examining Procedure (MPEP) § 1206 (8th ed, August 2001) ("[w]here an appeal brief fails to address any ground of rejection, appellants shall be notified by the examiner that he or she must correct the defect by filing a brief (in triplicate) in compliance with 37 CFR § 1.192(c)."). Instead of proceeding with an Answer, the examiner should have notified

appellants of the defect in their Brief, and provided them with an opportunity to correct the defect according to the rule. Accordingly, we remand the application to provide the examiner with an opportunity to address appellants' defective Brief.

While we take no position on the merits of this rejection, we note that his statement (Answer, page 7), questioning claim 5 and directing attention to page 8 of the specification is somewhat less than a clear statement of a rejection. Upon return of the application, we encourage the examiner to review the claimed invention together with the specification. If after this review the examiner believes that a rejection is necessary, the examiner should clearly state the basis for the rejection and provide appellants with an opportunity to respond. In this regard, we remind the examiner that the legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonably apprises those of skill in the art of its scope. See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

THE REJECTION UNDER 35 U.S.C. § 103:

In setting forth the basis for the rejection under 35 U.S.C. § 103 the examiner finds (Answer, page 5), "[t]he claims differ from Phillips [I] in that they recite a number of limitations directed to the structure of the test strip." The examiner, however, fails to explain which of the claimed test strip's structural limitations are not taught by Phillips I. Notwithstanding this position, the examiner finds (Answer, page 6), "[a]ll the reagents, structural limitations such as an aperture, and coated membrane are conventional in this art ... [and that]

[c]ombining various combinations of reagents and structural limitations in test strips is well known and both Phillips [I and II] teach many combinations of such elements."

The examiner's reliance on what is "well known" or "conventional in this art" suggests that the examiner's rejection is extended to include other references, not cited in the statement of the rejection. We remind the examiner that the question for us to consider is not whether appellants' claimed invention is "well known" or "conventional" but whether the claimed invention is prima facia obvious in view of the prior art relied upon by the examiner.

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."
>
> Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted]

In other words, "there still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited

prior art references for combination in the manner claimed.'" Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

For the forgoing reasons, we vacate the examiner's rejection and remand the application to the examiner to provide him with an opportunity to reevaluate his position in light of the correct legal standards.

If upon review of the file wrapper and other relevant documents, the examiner remains of the opinion that the claims on appeal are unpatentable, he should issue an appropriate Office action that sets forth the facts and reasons used in support of such a rejection.

In addition, we note that the rejection set forth in the Answer encompasses a plurality of claims but does not state with any specificity why any individual claim is unpatentable. If the examiner maintains a rejection under 35 U.S.C. § 103, we suggest the examiner review MPEP § 706.02(j) for a model of how to explain a rejection under this section of the statute. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable.

FUTURE PROCEEDINGS

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner which contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED

Sherman D. Winters	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Toni R. Scheiner	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Donald E. Adams	)
Administrative Patent Judge	)

DA/dym

Michael A Mann
Nexsen Pruet Jacobs & Pollard LLP
P.O. Box DRWR 2426
Columbia SC 29202-2426